K081201

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

MAY 28 2008

Device Name

Proprietary Device Name: Xpress3.cardiac.

Establishment Name and Registration Number of Submitter

Name: UltraSPECT Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	KPS
Subsequent Product Code	LLZ
CFR section:	892.1200
Panel Identification:	Radiology
Device Description:	Emission computed tomography system
Classification:	Class II Product

Reason for 510(k) Submission

Special 510(k) Submission

Identification of Legally Marketed Predicate Devices

WBR Xact.cardiac & Xpress.cardiac - K050815
including Half Dose K080784

Device Description

The Xpress3.cardiac is an image processing system, which is interfaced to gamma cameras. Gamma camera cardiac, fast acquired, data are reconstructed by the Xpress3.cardiac. The Xpress3.cardiac utilizes parallel and non – parallel beams and produce high resolution images. The images can be transferred to any other PACS device, which is DICOM or Interfile compatible.

Intended Use of Device

The Xpress3.cardiac is indicated for the acquisition, formatting and storage of scintigraphy camera output data. It is capable of processing and displaying the acquired information in traditional formats, as well as in pseudo three dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the image organs

Safety & Effectiveness

The device has been designed, verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that reconstructed images are equivalent or of better resolution comparing to images that are reconstructed by Filtered Back - Projection.

Substantial Equivalency

It is UltraSPECT opinion that the Xact.cardiac & Xpress.cardiac are substantially equivalent in terms of safety and effectiveness to the above predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

UltraSPECT, Ltd.
% Mr. Dan Laor
Managing Director
Quasar Quality, Ltd.
6 Sireni, Haifa, 32972
ISRAEL

Re: K081201
Trade/Device Name: Xpress3.Cardiac
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: April 22, 2008
Received: April 28, 2008

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081201

Device Name: Xpress3.Cardiac

Indications For Use:

The Xpress3.Cardiac is indicated for the acquisition, formatting and storage of scintigraphy camera output data. It is capable of processing and displaying the acquired information in traditional formats, as well as in pseudo three dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the image organs.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081201